FEB - 9 2012

510(k) Number: K112407 Summary Page 1 of 3

Date Prepared August 18, 2011

Submitter Information

Submitter's Name: Smiths Medical ASD, Inc.
Address: 1265 Grey Fox Road
St. Paul, MN 55112

Establishment Registration: 2183502

Contact Person: Thomas Bliss
Sr. Regulatory Affairs Specialist
Phone: (651) 628-7145
Fax: (651) 628-7457

Device Information

Trade Name:	Smiths Medical Peel-Away Sheath Introducers
Common Name:	Introducer Sets
Classification Name:	Catheter Introducer
Product Code:	DYB
Regulation:	21 CFR 870.1340

Predicate Device(s)

The predicate devices are the currently marketed Adelante® Brand Introducers manufactured by Oscor, Inc. and Smiths Medical Subclavian Introducer Sets.

The reference 510(k) numbers for these devices is provided below:

Predicate Device	510(k)
Adelante® Introducer Set Models: Adelante® and Adelante® S-Lite	K0073110
Smiths Medical Subclavian Introducers	K871132

Device Description

Each Smiths Medical Peel-Away Sheath Introducer consists of a dilator and a peelable sheath. Both the dilator and the sheath have a hub at the proximal end. The dilator slides inside the sheath and the hubs are engaged so that sheath and dilator may be manipulated as a single unit. One version of the Smiths Medical Peel-Away Sheath Introducer has a valve on the proximal end of the hub.

The introducers are available in French sizes ranging from 6 to 11. Interior diameters of the sheath range from .085 to .147 inches. Outside diameters range from .116 to .182 inches. The length of the dilator for the non-valved introducer is nominally 8 inches from hub to tip with a 6 inch sheath. The dilator for the valved introducer is 7 inches long with a 5 inch sheath.

The Peel-Away Sheath Introducer is used to facilitate the insertion of a catheter into the vascular system by dilating a vessel and introducing the sheath. The hubs are then disengaged and the dilator is removed leaving the sheath through which a catheter may be inserted. The sheath hubs are then broken and the sheath is peeled away and removed from the catheter.

Indications for Use

The Smiths Medical Peel-Away Sheath Introducers are indicated for the introduction of catheters into the vascular system.

Summary of Non-Clinical Testing

The non-clinical testing included assessment of the physical properties of the Peel-Away Sheath Introducer and its compatibility with co-packaged accessories. Biocompatibility assessment of the device was performed on the materials used to construct the introducers. The materials used in the introducer include PEBAX, polyethylene and polycarbonate. The valve used on valved introducers is made of silicone. The device is biocompatible based on the testing of the materials and reinforced by a history of use in the medical device industry.

Summary of Clinical Testing

Human clinical studies were deemed not necessary to evaluate the safety or effectiveness of the Smiths Medical Peel-Away Sheath Introducer.

Statement of Equivalence

The Smiths Medical Peel-Away Sheath Introducer is identical to the currently marketed Adelante® and Adelante® S-Lite Introducer and is packaged with accessories and in configurations substantially equivalent to the Subclavian Introducer currently marketed by Smiths Medical.

Conclusion

Based on the indications for use, technological characteristics, materials of construction, configuration and packaging, the proposed Smiths Medical Peel-Away Sheath Introducer is Substantially Equivalent to the identified predicate devices. Bench tests have confirmed compatibility with common accessories and conformance with specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 09 2012

Smiths Medical ASD, Inc.
c/o Mr. Thomas Bliss
Senior Specialist Regulatory Affairs
1265 Grey Fox Road
St. Paul, MN 55112

Re: K112407
Trade Name: Smiths Medical Peel-Away Sheath Introducers
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II (two)
Product Code: DYB
Dated: February 2, 2012
Received: February 6, 2012

Dear Mr. Bliss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

SMITHS MEDICAL ASD, INC.
510(k) Premarket Notification

Indications for Use Statement

510(k) Number: K112407

Device Name: Smiths Medical Peel-Away Sheath Introducers

Indications for Use:

The Smiths Medical Peel-Away Sheath Introducers are indicated for the introduction of catheters into the subclavian vein.

Prescription Use __X__ (Per 21 CFR 801 .109) AND/OR Over-The Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M & Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112407